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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,128	07/28/2005	Piotr Graczyk	102286.154US1	4053

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WILMERHALE/BOSTON
60 STATE STREET
BOSTON, MA 02109

EXAMINER

LOEWE, SUN JAE Y

ART UNIT	PAPER NUMBER
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1626

NOTIFICATION DATE	DELIVERY MODE
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07/03/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/509,128

Applicant(s)

GRACZYK ET AL.

Examiner

SUN JAE Y. LOEWE

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-13,16,28-30,32 and 64-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,6,9-13,28-30,32 and 64-66 is/are rejected.
- 7) ☒ Claim(s) 7,8 and 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4-21-2008.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-3, 5-13, 16, 28-30, 32 and 64-66 are pending in the instant application.

Response to Amendment/Arguments

2. Applicant's response and claim amendments have been fully considered. The amendment to the claims overcomes the following grounds of objection/rejection which are hereby withdrawn: a) claim objections (Sections 7 and 9-11, office action dated January 8, 2008); b) 35 USC 112 2nd paragraph (Sections 14-15, office action dated January 8, 2008). The amendment to the claims overcomes the 35 USC 112 1st paragraph rejections with respect to claims 7 and 8. The 35 USC 112 1st paragraph rejections are withdrawn for claims 7 and 8.

3. Applicant's arguments have been fully considered, however, they are not persuasive in overcoming the 35 USC 112 1st paragraph rejections with respect to claims 1-3, 5, 6, 9-13, 28-30, 32 and 64-66. The rejection with respect to these claims are maintained and hereby made FINAL. See response to arguments below.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on April 21, 2008 was in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. The IDS was considered. A signed copy of form 1449 is enclosed herewith. The crossed out non-patent literature references were not considered because copies were not provided. The crossed out US patent and publications were not considered because the identifying number did not correspond with the patentee/applicant names provided in form 1449.

Claim Objections

5. Claims 7, 8 and 16 objected to for depending on a base rejected claim, but would be allowable if re-written in independent form.

Claim Rejections - 35 USC § 112

6. Applicant has argued:

“ Applicants respectfully submit that the present specification also exemplifies compounds of formula (I) wherein R¹ is heterocyclyl or phenyl substituted with heterocyclyl. See, e.g., page 53 of the PCT application, Claim 16, first column & third row and second column & third row. ”

Applicant's response is noted. The scope of the disclosure is extended to include indole and benzo[d][1,3]dioxole. However, these two ring systems are not sufficiently representative of the genus of “heterocyclyl.” Applicant is respectfully referred to MPEP 2163.II.3.(a).(ii), excerpts below

A “representative number of species” means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure “indicates that the patentee has invented species sufficient to constitute the gen[us].” See *Enzo Biochem*, 323 F.3d at 966, 63 USPQ2d at 1615; *Noelle v. Lederman*, 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (Fed. Cir. 2004) (“[A] patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated.”). “A patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when ... the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed.”

It is maintained that the predictability in the instant field of endeavor is low; evidence indicates that one of ordinary skill could not predict the operability of the invention of any species other than those disclosed. The species disclosed are

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not representative of the broad genus claimed. For these reasons, it is maintained that the claims *prima facie* lack written description support. The 35 USC 112 1st paragraph rejections are still deemed to be proper and are hereby made FINAL. Claims 1-3, 5, 6, 9-13, 28-30, 32 and 64-66 remain rejected. This ground of rejection may be overcome by deleting “heterocyclyl” as an alternative from the definition of R’.

Conclusion

7. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUN JAE Y. LOEWE whose telephone number is (571)272-9074. The examiner can normally be reached on M-F 7:30-5:00 Est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sun Jae Y. Loewe, Ph.D./
6-23-2008

/Kamal A Saeed, Ph.D./

Primary Examiner, Art Unit 1626